

Amendments to the Claims:

This listing of the claims will replace all prior versions, and listings, of claims in the present application:

Listing of the Claims:

Claim 1 (currently amended): An orally deliverable pharmaceutical composition comprising a therapeutically effective amount of pramipexole or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient, said composition exhibiting at least one of (a) an in vitro release profile wherein on average no more than about 20% of the pramipexole is dissolved within 2 hours after placement of the composition in a standard dissolution test conducted according to USP 24 using Apparatus 1 with a spindle rotation speed of 100 rpm and a dissolution medium of 0.05M phosphate buffer, pH 6.8, at 37°C; and (b) an in vivo pramipexole absorption profile following single dose oral administration to healthy adult humans wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours.

Claim 2 (cancelled)

Claim 3 (original): The composition of claim 2 wherein no more than about 12% of the pramipexole dissolves within 1 hour in said test.

Claim 4 (original): The composition of claim 2 wherein time to reach 50% dissolution is at least about 4 hours.

Claim 5 (original): The composition of claim 2 wherein time to reach 50% dissolution is at least about 6 hours.

Claim 6 (original): The composition of claim 2 wherein time to reach 50% dissolution is at least about 8 hours.

Claim 7 (original): The composition of claim 2 wherein time to reach 50% dissolution is at least about 12 hours.

Claim 8 (original): The composition of claim 1 that exhibits an in vivo pramipexole absorption profile following single dose oral administration to healthy adult humans wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours.

Claim 9 (original): The composition of claim 8 wherein the time to reach a mean of 40% absorption is at least about 5 hours.

Claim 10 (original): The composition of claim 8 wherein the time to reach a mean of 40% absorption is at least about 6 hours.

Claim 11 (original): The composition of claim 1 that, when administered once daily, exhibits a bioavailability substantially equivalent to an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation, administered three times a day.

Claim 12 (original): The composition of claim 1 that, following single dose administration of 0.375 mg, expressed as pramipexole dihydrochloride monohydrate equivalent, exhibits a maximum plasma concentration (C_{\max}) of pramipexole that is not greater than about 0.3 ng/ml.

Claim 13 (original): The composition of claim 1 that exhibits a time to reach maximum plasma concentration (T_{\max}) of pramipexole that is at least about 6 hours following administration of the composition.

Claim 14 (original): The composition of claim 1 that exhibits a time to reach maximum plasma concentration (T_{\max}) of pramipexole that is at least about 8 hours following administration of the composition.

Claim 15 (original): The composition of claim 1 that exhibits a pharmacokinetic profile consistent with steady-state plasma concentrations having a fluctuation ratio that is not substantially greater than that of an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation, administered three times a day.

Claim 16 (original): The composition of claim 1 that comprises release-modifying means effective to provide said in vitro release profile and/or said in vivo pramipexole absorption profile.

Claim 17 (original): The composition of claim 16 wherein said release-modifying means is selected from the group consisting of a polymer matrix wherein the pramipexole is dispersed; a release-controlling layer or coating; and an osmotic pump.

Claim 18 (original): The composition of claim 1 wherein the pramipexole is in a form of a pharmaceutically acceptable salt thereof having moderate to high solubility in water.

Claim 19 (original): The composition of claim 18 wherein said salt is pramipexole dihydrochloride.

Claim 20 (original): The composition of claim 1 that is in the form of discrete dosage units.

Claim 21 (original): The composition of claim 20 wherein the amount of pramipexole in each dosage unit is sufficient to provide a daily dose in one to a small plurality of dosage units administered at one time.

Claim 22 (original): The composition of claim 20 wherein a full daily dose is contained in a single dosage unit.

Claim 23 (original): The composition of claim 20 that comprises about 0.1 to about 10 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

Claim 24 (original): The composition of claim 20 that comprises about 0.2 to about 6 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

Claim 25 (original): The composition of claim 20 that comprises about 0.3 to about 5 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

Claim 26 (withdrawn): A method of treatment of a subject having a condition or disorder for which a dopamine receptor agonist is indicated, the method comprising orally administering to the subject, not more than once daily, the composition of any of the preceding claims.

Claim 27 (withdrawn): The method of claim 26 wherein the condition or disorder is Parkinson's disease or a complication associated therewith.